

K962969/S1



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DEC - 6 1996

510 (k) SUMMARY

APPLICANT: Medical Device Technologies, Inc.
4445-310 SW 35th Terrace
Gainesville, FL 32608

CONTACT: Karl Swartz
Quality Assurance Manager

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TRADE NAMES: Medical Device Technologies, Inc. Ultra™

COMMON NAME: Reusable handle gun for use with
disposable biopsy needles.

CLASSIFICATION NAME: Instrument, Biopsy, No. 78KNW

SUBSTANTIAL EQUIVALENCE:

<u>Company Name</u>	<u>Product Name</u>	<u>510 (k) No.</u>
Manan Medical Products	Pro Mag 2.2	K914874
C.R. Bard	Biopty Biopsy System	K871390

DESCRIPTION OF DEVICE:

Our company is presently authorized by the Food and Drug Administration to manufacture disposable soft tissue biopsy needles, K921418. This device is to be the reusable handle gun that will compete with the products that currently use the biopsy needles covered by this 510(k).

The Ultra™ Biopsy Device is used to obtain multiple core samples from soft tissue such as the liver, kidney, prostate, breast, and various soft tissue lesions. It is not intended for bone.



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